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IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., and NORTON (WATERFORD) LTD.,

Civil Action No. 2:24-cv-00909 (SRC)(MAH)

Plaintiffs,

v.

CIPLA USA, INC. and CIPLA LTD.,

Defendants.

STIPULATION AND [PROPOSED] ORDER

Plaintiffs Teva Branded Pharmaceutical Products R&D, Inc. ("Teva") and Norton (Waterford) Ltd. ("Norton") (collectively, "Teva") and Defendants Cipla USA, Inc. and Cipla Ltd. (collectively, "Cipla"), by their undersigned counsel, stipulate and agree as follows:

WHEREAS, after receiving Notice of Paragraph IV Certifications from Cipla, which seeks regulatory approval of Cipla's beclomethasone dipropionate metered aerosol inhalation products, Teva filed a Complaint asserting infringement of U.S. Patent Nos. 8,132,712 (the "'712 patent"), 8,931,476 (the "'476 patent"), 10,022,509 (the "'509 patent"), 10,022,510 (the "'510 patent"),

10,086,156 (the "'156 patent"), 10,561,808 (the "'808 patent"), 10,695,512 (the "'512 patent"), 10,792,447 (the "'447 patent"), 11,395,888 (the "'888 patent"), 11,395,889 (the "'889 patent"), 11,559,637 (the "'637 patent"), and 11,583,643 (the "'643 patent") in Civil Action No. 2:24-cv-00909 (SRC)(MAH) ("this Action"), which are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") in connection with Plaintiffs' QVAR RediHaler® (beclomethasone dipropionate, 40 mcg) product pursuant to 21 U.S.C. § 355.

WHEREAS, Cipla's responsive pleading in this Action is due on or before April 22, 2024.

WHEREAS, no earlier than March 16, 2024, Teva received a Notice of Paragraph IV Certification from Cipla relating to U.S. Patent Nos. 11,793,953 (the "'953 patent") and 11,865,247 (the "'247 patent") in connection with Cipla's efforts to seek regulatory approval of Cipla's beclomethasone dipropionate metered aerosol inhalation products.

WHEREAS, Cipla intends to serve a Notice of Paragraph IV Certification relating to U.S. Patent No. 11,896,759 (the "'759 patent") in connection with Cipla's efforts to seek regulatory approval of Cipla's beclomethasone dipropionate metered aerosol inhalation products.

WHEREAS, Teva represents that it intends to file a Complaint asserting patent infringement stemming from Cipla's Notices of Paragraph IV Certification relating to the '953 patent, the '247 patent, and the '759 patent.

NOW THEREFORE, Teva and Cipla hereby stipulate and agree, subject to the approval of the Court, as follows:

1. To conserve judicial resources, Teva and Cipla agree to consolidate this Action with the forthcoming Complaint relating to Cipla's Notices of Paragraph IV Certification in connection with the '953 patent, the '247 patent, and the '759 patent, for all purposes, including discovery, case management, and trial, subject to further order of the Court.

- 2. Teva agrees to file the Complaint relating to the '953, '247, and '759 patents on or before May 17, 2024.
- 3. The parties agree that Cipla shall have until June 14, 2024, to file a combined answer, move or otherwise respond to the above referenced Complaints.

Respectfully submitted,

Dated: April 22, 2024

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SO ORDERED.

Hon. Michael A. Hammer, U.S.M.J.